Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Aranesp (darbepoetin alfa)

Override(s)	Approval Duration
Prior Authorization	6 months

Medications
Aranesp (darbepoetin alfa)

APPROVAL CRITERIA

Requests for Aranesp (darbepoetin alfa) may be approved if the following criteria are met:

I. Individual has a baseline hemoglobin (Hgb) level are less than 10 g/dL; **AND**
II. Baseline iron status is adequate as defined by one of the following:
   A. Transferrin saturation 20% or greater; **OR**
   B. Ferritin 80ng/mL or greater; **OR**
   C. Bone marrow demonstrates adequate iron stores; **AND**
III. Individual is using for one of the following:
   A. Anemia associated with chronic kidney disease (CKD), for individuals on dialysis, to achieve and maintain Hgb levels within the range of 10 to 11g/dL; **OR**
   B. Anemia associated with CKD for individuals **not** on dialysis, to achieve and maintain Hgb of 10g/dL; **OR**
   C. Myelosuppressive chemotherapy when the following are met:
      1. Chemotherapy is planned for a minimum of 2 months; **AND**
      2. Individual has a diagnosis of non-myeloid cancer and the anticipated outcome is not cure; **OR**
   D. Myelodysplastic syndrome with endogenous erythropoietin level less than 500 mU/mL (NCCN 2A).

Requests for Aranesp (darbepoetin alfa) may **not** be approved for all of the following:

I. Continued use when the Hgb level exceeds 11 g/dL unless otherwise specified (for example, pediatric individuals with CKD where target Hgb levels within the range of 10 to 12 g/dL); **OR**
II. Individuals with uncontrolled hypertension;
III. Use beyond 12 weeks in the absence of response in individuals with chronic kidney disease; **OR**
IV. Use beyond 8 weeks in the absence of response in individuals with myelodysplastic syndrome (MDS) ; **OR**

Market Applicability							
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Applicable	X	X	X	X	X	X	NA

V. Use beyond 8 weeks in the absence of response or if transfusions are still required in individuals with metastatic, non-myeloid cancer being treated with myelosuppressive chemotherapy agents known to produce anemia;
VI. As treatment in the presence of a sudden loss of response with severe anemia and low reticulocyte count; **OR**
VII. To treat anemia individuals with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion; **OR**
VIII. Continued use beyond 6 weeks after therapy with myelosuppressive chemotherapy known to produce anemia is completed.

Note:
Erythropoiesis-stimulating agents (ESAs) have black box warnings for an increased risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and tumor progression or recurrence.
For CKD: In controlled trials, individuals experienced greater risks for death, serious adverse cardiovascular reactions and stroke when ESAs were administered to target a Hgb level greater than 11 g/dL. Use the lowest dose needed to reduce the need for red blood cell (RBC) transfusions.
For Cancer: In controlled trials, ESAs shortened overall survival and/or increased the risk for tumor progression or recurrence in individuals with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers. Use the lowest dose needed to avoid RBC transfusions. Use ESAs only for anemia from myelosuppressive chemotherapy when the anticipated outcome is not cure and discontinue ESAs following completion of a chemotherapy course.
For Perisurgery: Deep venous thrombosis (DVT) prophylaxis is recommended due to increased risk for DVTs.

ESAs are contraindicated in individuals with uncontrolled hypertension. Blood pressure should be adequately controlled prior to initiation and during treatment with ESAs.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

1. Bohlius J, Bohlke K, Castelli R, et al. Management of cancer-associated anemia with erythropoiesis-stimulating agents: ASCO/ASH clinical practice guideline update. *J Clin Oncol.* 2019;37(15):1336-1351.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 13, 2019.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

5. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Inter*. 2012; Suppl 2: 279–335. Available from: https://www.kidney.org/professionals/guidelines/guidelines_commentaries/anemia. Accessed on: June 13, 2019.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 13, 2019.
    - Hematopoietic Growth Factors. Version 2.2019. Revised March 27, 2019.